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Objectives: Methods are developed to establish minimum performance standards, calibration intervals, and criteria for exposure control for a whole breast digital mammography system.
Methods: A prototype phantom was designed, and an automatic method programmed, to analyze SNR, resolution, and dynamic range between CCD components in the image receptor and over time. The phantom was imaged over a 5 month period and the results are analyzed to predict future performance. White field recalibration was analyzed by subtracting white fields obtained at different intervals. Exposure effects were compared using the prototype phantom for different kVp, filtration (Mo vs. Rh) and mAs.
Results: Resolution tests, when Mo anode/Mo filter combinations are used will require daily phantom imaging. If Mo anode/Rh filter techniques are used, weekly imaging will suffice. Differences between CCD performance are greater (12%) than differences in a single CCD over time (6%). White field recalibration is needed weekly because of artifacts, which occur if longer intervals between recalibration occur. Higher kVp and Rh filtration give markedly better phantom performance than Mo filtration at 26 kVp and are recommended for clinical exposures.
Conclusions: Phantoms for digital mammography units should cover the entire image receptor, should test intersections between components of the receptor, and should be imaged more frequently than current recommendations for screen/film systems.

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Carolyn Kimmel-Smith 9/29/97

PI - Signature Date

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Year 1 Annual Report of Routine Quality Assurance for Whole Breast Digital Mammography

C. Kimme-Smith, PhD
UCLA Department of Radiological Sciences

INTRODUCTION

The promise of commercially available whole breast digital mammography has fueled many research projects during the last five years. This research has provided design tools for manufacturers of digital mammography equipment and has encouraged medical physicists to predict preliminary criteria for its performance (1-4). In addition, the wide use of digital stereotactic breast equipment has introduced medical physicists to calibration and exposure problems (5,6).

Because digital mammography image receptor contrast can be increased after image acquisition, contrast is only limited by noise and subject contrast requirements. For this reason, it has been predicated that beam spectra and kVp can be higher than those used for screen-film mammography (7). These values will depend on the conspicuity of masses in their surround, and will be expected to vary with breast composition and compressed breast thickness (8). Experiments with contrast/detail phantoms (9) and phantoms designed specifically for digital mammography (3) have shown the dependence of image performance, signal to noise, and calcification visibility with exposure.

Current clinical trials of whole breast digital mammography equipment have modeled quality control procedures on Mammography Quality Standards Act guidelines (10,11). The FDA is encouraging QA of these digital systems in a document entitled, "Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems." Clinical exposures in these trials usually produce the same mean glandular dose required for screen-film, although beam spectra is sometimes harder and/or kVp higher, depending on the manufacturer. These preliminary standards will be replaced with standards developed as a result of clinical experience with digital mammography equipment. At our institution, we have tested a variety of quality control procedures on a TREX digital mammography unit over a five month period. During this time, we have developed methods for predicting minimum performance standards, frequency of testing and calibration, and criteria for exposure control which may be useful guidelines for other whole breast digital systems.

METHODS

The TREX (Copiague, NY) whole breast digital mammography system consists of an array of 12 CCDs arranged in a 3 x 4 grid to produce an array 18 x 24 cm in size with 4800 x 6800 14-bit pixels. Each CCD pixel is in contact with a fiber optic taper which connects it to the CsI screen. The CsI is also in discrete packages whose boundaries are not aligned with CCD boundaries. The TREX system has a permanently installed reciprocating grid with a 5:1 grid ratio and 35 strips per cm. The digital image receptor is mounted on a LORAD (Danbury, CT) M4 mammography unit supplying both Mo and Rh filtration to a Mo anode. The non-digital portion of this unit was calibrated according to MQSA regulations.

Each mammography view is displayed on an acquisition workstation, archived to an optical disk, and transmitted to PACS storage. A diagnostic workstation is currently being clinically tested; routine clinical diagnosis is performed from films produced by a prototype Agfa 40 μ laser (Ridgefield Park, NJ). The diagnostic workstation also supports a quality control program designed at UCLA for the TREX system.

Because of the 12 independent CCDs which make up the digital image, a phantom was designed with 12 modules so that each CCD could be tested independently (Figure 1).

Each module consists of a low contrast 1 cm^2 pad and eight aluminum oxide calcifications, four of which are .32 mm in diameter and four are .24 mm in diameter (the size of the third and fourth speck groups of the American College of Radiology Mammography Accreditation phantom). In addition, a 16 lp/mm gold phantom lies on the intersection between two CCDs, and four aluminum wedges (14 steps, each 400 μm high) lie on the intersections between eight CCDs. The line pair phantom and step wedges are primarily for acceptance testing the digital unit, while the contrast pads and calcifications calibrate routine quality control. Two exposures were made whenever the phantom was imaged: the Mo anode/Mo filter imaged the phantom at 28 kVp, 65 mAs, to yield a mean glandular dose of 186 mrads, and a Mo anode/Rh filter exposure was made at 28 kVp, 85 mAs (the mR/mAs is lower with this anode/filter combination) to give a MGD of 177 mrads. Exit exposures (i.e., exposure to the grid and thence to the image receptor) were measured with the phantom elevated above the ion chamber with a 10 cm air gap between the two objects. The Mo/Mo exit exposure was 28R while the Mo/Rh exit exposure was 33R, corresponding to the different absorption in tissue of the different energy spectra.

A computer program calculates quality measures from each contrast pad. The calculations found most useful are the mean divided by the standard deviation within a 50 pixel on a side square in the pad, as well as a signal to noise ratio (SNR) consisting of the contrast of the pad to the background divided by the standard deviation (noise) in quadrature:

$$SNR = \frac{| \mu_{in} - 1/2 (\mu_{out_1} + \mu_{out_2}) |}{1/2 \sqrt{(\sigma_{out_1} + \sigma_{out_2})^2 + \sigma_{in}^2}}$$

where the subscript "in" references data collected from the 50 x 50 pixels within the contrast pad and "out 1" and "out 2" reference data collected from two 50 x 50 pixel regions located adjacent to the contrast pad. In addition, the fourth CCD module contains two additional contrast pads so that intra-CCD variation can be studied. Twelve groups of 8 specks each are also magnified to full resolution by the analysis computer program so that they can be visually graded. The targets are fixed on a 3 mm thick plate of acrylic which is placed on 3.6 cm of acrylic. Care must be taken to position the phantom precisely so that wedges and line pair phantoms are aligned with CCD boundaries. The thickness of the phantom is matched to the acrylic block used to calibrate and correct CCD sensitivity variations.

In addition, in order to recalibrate CCD sensitivity, a 3.6 cm thick sheet of Lucite is imaged eight times once a week and a flood field (white field) is formed from the pixel by pixel average of the 8 samples. This white field is then used to normalize CCD response for all digital images acquired by the system. Just as Nuclear Medicine gamma cameras are periodically recalibrated to normalize sensitivity differences, digital systems must be periodically recalibrated to normalize CCD sensitivity. The interval needed between this recalibration has not been established, and for different digital equipment, different intervals are common. For the Fischer (Denver, CO) digital stereotactic biopsy unit, daily white field calibration is common, while the LORAD digital stereotactic unit usually requires biannual recalibration. The TREX system is currently recalibrated weekly. To determine if this frequency is necessary, an initial white field was subtracted pixel by pixel from similar white fields obtained on the same day, at one week, two week, three week, six week, two month and three month intervals. The resulting differences were accumulated in a histogram; the mean, standard deviation, and maximum difference between pixels were tabulated. Because the white field consists of 6 areas on the CCD array, corresponding to different electronic modules, comparisons were also made between

these modules to determine if a particular part of the image receptor was more subject to changes in sensitivity than other parts.

Finally, to determine the effects of energy spectrum and photon flux on digital receptor performance, a series of exposures at 26-32 kVp, with Mo and Rh filtration, were made with matching mean glandular doses or matching exit exposures. The performance of the phantom was compared for these techniques and for increasing mean glandular dose in order to make recommendations for future clinical trials.

RESULTS

Minimum performance standards.

At the present time, whole breast digital mammography performance is being compared to that of screen-film mammography. In order to justify the increased costs of these systems, improved performance should be expected once they are commercially available. All three currently tested manufacturers' image receptor methods have superior performance to that of screen-film when images of phantoms are compared (3,9,12). In addition, the ACR accreditation procedure for digital stereotactic accreditation requires that these units be able to image the fourth speck group, rather than the third group, which is required for screen-film systems (13). Thus one minimum requirement for whole breast digital systems should be the ability to image aluminum oxide specks .24 mm in diameter. This standard varies less than the more quantitative performance criteria, of μ/σ and SNR, with varying technique (see "Calibration Intervals," below). Minimum subject contrast or signal to noise is more difficult to assess. For the TREX system, using the prototype phantom, μ/σ varied from 43 to 90 depending on kVp, filtration, and photon fluence. Signal to noise ratio, defined earlier, varied from .4 to 2.5 for the low contrast pads employed on our phantom. Note that for the TREX system, a high photon fluence exposure yields a low gray level value, so for the exposure results reported here, all gray level values have been reversed so that high photon fluence corresponds to a high gray level value.

The line pair phantom performance represents the MTF at high contrast values and so does not reflect the performance at the 50% level, where calcification detection occurs. As such, it is not as relevant a criterion for clinical performance as the aluminum oxide specks. Despite a pixel pitch of 43 microns, the line pair phantom was consistently 9 lp/mm when magnified by resting on 3.9 cm of acrylic. Focal spot measurements showed the screen-film limiting resolution as 15 lp/mm with the same geometry (i.e., lines parallel to the anode-cathode direction).

Dynamic range, measured with the four step wedges shared by eight CCDs, is also dependent on exposure parameters. As exit exposure increases, the number of steps with more than 50 average gray level differences varied from 6 to 12. Dynamic range varied between CCD's by no more than 100 gray level values (out of 2^{14}).

On acceptance testing, discontinuities at the CCD boundaries can best be measured by a fluoroscopy or mammography mesh placed diagonally across the intersections. Assessment of the variations between CCDs requires non-clinical window and leveling. In the prototype phantom, straight edges perpendicular to the CCD boundaries, such as the line pair phantom and step wedges (Figure 1), do not assess these discontinuities as well as a diagonally placed mesh image because the interpolation algorithm includes pixels perpendicular to the boundary and thus tends to smooth the artifact successfully when tested with targets aligned perpendicular to the boundary.

Calibration Intervals

For phantom imaging, the number of high contrast line pairs visible did not change over the five month period, while the number of wedge steps rarely changed by even one step (or 50 gray levels). Variations between SNR measurements made on the same CCD with the identical exposure varied less than .7%, while variations between CCDs on the

same day varied up to 12.4%. Phantom measurements were made daily for 6 weeks, and then three times a week for the remaining time. The largest variation for one of the CCDs was 6.3% over the five months of testing. Clearly, variations between CCDs was greater than variations in one CCD over time.

Calcification speck count varied by up to 4 specks over time, indicating that automatic counting rather than visibility should be used for this target (14). Visibility of the 0.24 mm specks was more likely to fail for the Mo/Mo exposure. The phantom images made with the Rh filter always revealed from 1 to 4 of these smaller specks, while they were not visible in at least one CCD 8 out of 12 times for Mo filter images. Overall, .5 more calcifications (out of 8) were found with the Rh filter images than for the Mo filter images. If we use the criterion that the 0.24 mm specks must be visible for digital imaging to ensure that its quality is equal to that of stereotactic breast biopsy imaging, then daily phantom imaging would be needed for Mo filtration. If Rh filtration was used, then less frequent phantom imaging would be needed to ensure continuing good resolution.

The SNR, averaged over the 12 CCD values on any given day, are likely to vary from the preceding test day's values from .03 to .05 (see Table 1). While the coefficient of variation of the 12 CCDs on any given test day varies from 7 to 15%; CCDs which contribute to this variation recover their previous values on subsequent days. Over the 6 month period that the phantom was tested, SNR for individual CCDs had a coefficient of variation of 4% to 6.3% for the Mo/Mo images and 3.7% to 7.6% for Mo/Rh images (see Table 2). This variation exceeds the reproducibility recommendation for automatic exposure control given in the medical physicist tests under MQSA (11). However, it is much less than variations over all 12 CCDs (Table 1). These variations may be partly due to the heel effect. While deterministic variations in photon flux are normalized by dividing each pixel by the matching white field pixel, photon noise is likely to be higher when photon flux is less. CCDs in the last row, closest to the anode end of the x-ray tube, are most affected by this phenomena. Thus CCDs 9, 10, 11, 12 have consistently lower SNR values (Table 1). Because the position of the contrast pad and the "outside" regions of interest where noise is calculated are found automatically, variations due to the position of each 50 x 50 pixel are not responsible for these differences.

Without a failure in the whole breast digital system which still allowed digital images to be formed, failure criteria for SNR cannot be made. We can state, however, that the variations in SNR in the TREX system during the five months test period did not affect clinical images and so may be taken as acceptable variations. The interval for testing during the last three and a half months has been three times a week. If testing occurred weekly, variations would be nearly identical.

White field calibration interval was compared by subtracting white fields obtained at different time intervals. To ensure that the six segments of the white field did not vary in their performance from each other, each was analyzed independently for one week to three week intervals. The two parts which varied most are documented in Table 3 for the Mo filter white field. The behavior of the Rh filter white field is surprisingly similar. When all 6 partitions of the white field are analyzed together over a longer interval, Table 4 reports the resulting statistics. Note that at a one week interval mean and S.D. are similar to recalibration on the same day, but that for longer intervals these factors increase up to 60%. In addition, increasing pixel drop-out, similar to screen/film pick-off, occurs if recalibration is not performed weekly.

The most interesting results occurred when four different techniques with varying energy spectra and photon fluence were compared using the prototype phantom. Table 5 reports the techniques tested, mean glandular dose, exit exposures, and phantom scores which resulted. If the grid has a Bucky factor of 2, then the lowest exit exposure delivers only 6 mR to the CsI screen, while the two higher exposures give 16 mR each, twice the exposure needed by a 100 speed mammography screen/film system.

CONCLUSIONS

Variations in SNR across the image receptor vary more than do screen/film systems, so the whole image receptor should be tested. For digital systems employing discrete partitions, such as separate CsI elements, multiple CCDs, or electronic modules, phantoms should test these partitions and their boundaries. When low dose, low energy spectra techniques are employed, more frequent phantom testing may be necessary if greater resolution criteria are mandated for digital mammography than those applied to screen/film systems. Specifically, exposures of 26 kVp, Mo anode/Mo filtration and MGD of 91 mrem require weekly phantom imaging if the fourth group of specks in the ACR mammography accreditation phantom must be visible.

Geometrical distortions can be evaluated with the mammography screen/film contact test mesh placed obliquely on the breast support platform with 4 cm of acrylic. Because of increasing changes in CCD pixel sensitivity over time, weekly white field recalibration is recommended. Increased energy spectra and photon flux will improve digital mammography performance for these early prototype systems. These increases are still within MQSA dose recommendations, except in California, where a 200 mrem limitation would require the use of Mo/Rh anode/filter combinations. Medical physicists may wish to measure exit exposures for these systems in order to calibrate optimal exposures for varying sized breasts. Preserving subject contrast by limiting the kVp and filtration is apparently not as significant for digital systems. However, contrast enhancement is limited by noise and image receptor artifacts so that kVp above 32 is not recommended.

MQSA regulations for digital mammography must be based on realistic tests of this equipment and not on historical criterion established for screen/film systems.

Table 1. SNR for 12 CCDs over one week for Mo/Mo and Mo/Rh exposures.

	CCD	1	2	3	4	5	6	7	8	9	10	11	12	μ	σ *	cov **
Mo/Mo	Aug 6	1.18	1.08	1.08	0.97	1.03	0.98	1.02	1.02	0.88	0.84	1.00	0.89	0.998	.095	9.6%
	Aug 8	1.27	1.13	1.11	1.00	1.06	1.00	1.07	0.94	0.93	0.92	1.05	0.86	1.033	.126	12.2%
	Aug 11	1.31	1.06	1.12	1.08	1.01	0.99	1.07	1.05	0.84	0.89	1.11	0.89	1.035	.126	12.2%
Mo/Rh	Aug 6	1.51	1.32	1.23	1.31	1.18	1.24	1.01	1.17	1.10	1.02	1.00	1.05	1.178	.15	13%
	Aug 8	1.40	1.20	1.22	1.21	1.16	1.08	1.09	1.03	1.05	1.05	1.01	1.01	1.126	.12	10%
	Aug 11	1.42	1.28	1.32	1.31	1.22	1.16	1.21	1.06	1.12	1.11	1.16	1.14	1.209	.105	8.7%

* σ = standard deviation

** cov = coefficient of variation = $\sigma/\mu * 100$

Table 2. Coefficient of variation for the 12 CCDs over a five month test period for SNR.

CCD:	1	2	3	4	5	6	7	8	9	10	11	12
Mo/Mo	4.81	4.37	4.85	3.99	5.46	4.43	4.25	4.81	5.55	5.60	6.27	5.34
Mo/Rh	4.37	5.92	3.95	3.69	6.42	7.48	5.24	3.80	5.67	7.63	6.71	6.70

Table 3. Whilte field partition variations over one to three week intervals for a Mo/Mo anode/filter combination.

Partition 1

Interval	Mean difference	S.D.	Maximum difference
1 week	12.94	11.34	2070
2 weeks	22.44	16.53	2487
3 weeks	28.37	18.96	2264

Partition 2

Interval	Mean difference	S.D.	Maximum difference
1 week	12.03	11.78	3061
2 weeks	18.61	16.81	3088
3 weeks	24.92	20.64	3097

Table 4. White field variations over a same day period and a three month period for a Mo/Mo anode/filter combination.

Interval	Mean difference	S.D.	Maximum difference
Same day	13.38	11.90	1973
1 week	12.95	11.78	3061
2 weeks	20.21	17.75	3256
3 weeks	20.21	17.75	3181
14 weeks	33.67	66.22	3362

Table 5. Effect of increasing energy spectra and photon fluence on calcification detection and SNR.

Anode/ Filter	kVp	mAs	MGD*	EE**	SNR***	Calcifications Detected+
Mo/Mo	26	45	91	12	.599	4.25
Mo/Mo	28	45	129	18	.780	6.25
Mo/Mo	28	90	260	32	1.249	8.00
Mo/Rh	28	90	188	32	1.866	8.00

* MGD is mean glandular dose (in mrem).
** EE is exit exposure 5 cm above image receptor (in mR).
*** SNR is the average signal to noise ratio over all 12 CCDs.
\+ Calcifications detected are averaged over all 12 CCDs.

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Figure Captions

1. Schematic of 18 x 24 cm phantom designed to test all 12 CCDs for the TREX full field digital mammography unit. Multiple targets at the lower right hand side test intra-CCD performance.

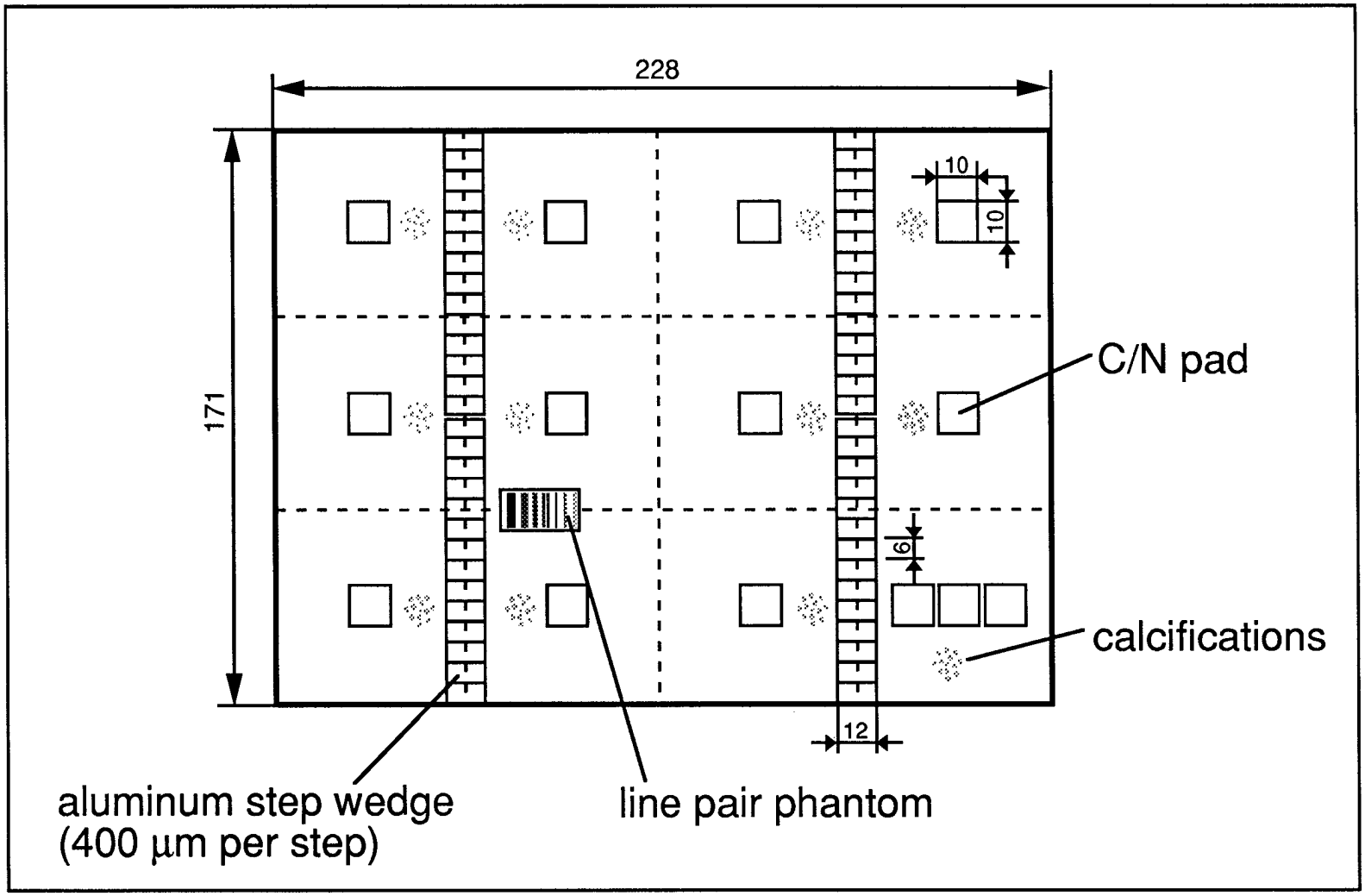
228
171
10
10
C/N pad
6
calcifications
12
aluminum step wedge
(400 µm per step)
line pair phantom

Figure 1